

REGENYAL
idea

Bio-expander



CROSS-LINKED
HYALURONIC ACID

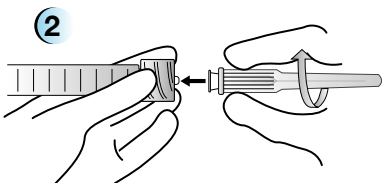
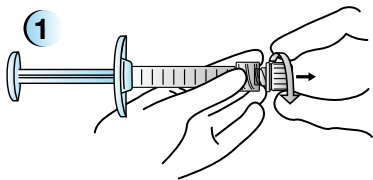
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LABORATORIES

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The product is solely intended to be used by medical personnel. Do not use for applications other than indicated in this package leaflet.

DESCRIPTION

Regenyal Idea Bio-Expander is a resorbable medical device (sterile, apyrogenic and physiological gel) to be used as filler for the correction of medium and deep skin sagging on the face and to increase lip volume and contour. The main component is cross-linked hyaluronic acid of non-animal origin, produced by bacterial fermentation.

COMPOSITION

Cross-linked hyaluronic acid 25 mg/g
Phosphate buffered saline, water for injectable solutions q.s.1 g

PACKAGE 3x1.1ml

- package leaflet
- 3 sealed blisters each containing 1 single-dose/single-use pre-filled sterile syringe
- adhesive tabs to be applied to the patient card for product traceability
- 1 needle and 1 cannula

METHOD OF ACTION

Regenyal Idea Bio-Expander is injected into the skin tissue for the supplementation of the extracellular matrix and to increase intracutaneous volume, or for the treatment of cutaneous depressions due to wrinkles and scarring.

INTENDED USE

Regenyal Idea Bio-Expander is an implantable medical device produced in compliance with Directive 93/42/EEC MDD, intended for the treatment of imperfections in the following areas of the face:

- nasolabial folds
- perioral wrinkles
- acne and facial scars
- glabellar wrinkles
- forehead wrinkles
- areas of the face requiring enrichment of the facial tissue (ex. cheeks, chin, cheekbones, lips) with a temporary increase in volume of the soft tissues.

The outcomes of the procedure depend on skin type and the nature of the blemishes, with results being the better the less noticeable the nature of the defect.

DIRECTIONS FOR USE

Prior to any procedure with Regenyal Idea Bio-Expander, the doctor must conduct adequate anamnesis and an overall assessment of the patient's condition, to ensure the absolute absence of contraindications to the implant.

The areas to be treated must be identified and assessed based on criteria to do with lines and symmetry one must adhere to.

The procedure may be performed under local anaesthesia for lip treatments in order to ensure the necessary comfort to the patient.

The physician should inform the patient beforehand on the methods of the procedure, its nature, warnings, precautions and possible individual outcomes, the potential adverse responses, the expected duration of the implant and the possible need for supplementary procedures for maintenance and/or detailed definition of the result achieved. The area of the procedure should be cleaned with antiseptic solutions before implantation.

Extract the syringe from the blister, remove the top as shown in the figure and screw the needle or the cannula to the luer-lock, complete with protection.

Only remove the cover just before performing the procedure.

Regenyal Idea Bio-Expander is administered with a sterile needle compliant with Luer-Lock standards with standardised fittings, included in the package.

The implant should be performed in the top/middle dermis; the procedure is, however, at the physician's discretion and depends on the correction to be performed and the chosen implantation method.

At the end of the procedure it is advisable to perform a gentle massage of the treated area for the implant to be optimally.

DOSE AND ADMINISTRATION

The volumetric markings on the syringes have indicative purposes, and the dosage to be used for the individual case is at the doctor's discretion. The frequency with which to repeat the procedure depends on several factors, concerning both the patient's physiology (skin type, individual metabolism, anatomy, age) and lifestyle. Another factor to be taken into account is related to the chosen implant techniques. The procedure should be repeated periodically in order to maintain the results achieved, every 6-12 months.

PRECAUTIONS

The usual precautions in case of percutaneous procedures must be taken during the procedure. The risks are those of common infection related to the type of treatment.

Regenyal Idea Bio-Expander must not be used on patients suffering from:

- infectious or inflammatory processes close to the area of the procedure
- known hypersensitivity to Keloids
- allergy to components
- immune system disorders
- chronic pathological skin condition
- conditions affecting the clotting factors or in the case of anticoagulant therapy in progress.

Around the time of treatment, the patient should avoid taking substances (Aspirin, NSAIDs, Vit. E) that act on blood fluidity, in order to reduce to the minimum the likelihood of bruising or bleeding of the injected areas. The use of Regenyal Idea Bio-Expander is strictly excluded in areas where there are mammary, tendon, bone and muscle implants. After treatment, and until swelling and redness go away completely, the implanted areas should not be exposed to excessive heat (sun, UV tanning sessions, laser), or to intense cold.

After use dispose of needles and syringes according to the indicated procedures for hospital waste.

ADVERSE REACTIONS, WARNINGS AND CONTRAINDICATIONS

As is the case for percutaneous injections, there may be phenomena of:

- inflammatory reaction (redness, oedema, etc.), sometimes associated with itching and pain to the touch;
- haematomas;
- hardening or lumps at the injection site;
- skin colouring or discolouring at the injection site;

These phenomena generally resolve in few days. Should they persist more than a week, the patient must promptly contact his/her doctor.

Regenyal Idea Bio-Expander must be used intracutaneously and must not be injected into blood vessels.

No overdosage phenomena or interaction with medicinal products are known.

Do not use during pregnancy.

Regenyal Idea Bio-Expander is available in sterile single use packages.

It is forbidden to reuse the content for subsequent applications or on other patients.

The product must be used immediately after opening.

Any unused product must be disposed of.

Do not use the product if the package is damaged.

Do not mix with other injectables, nor use other implants in conjunction with Regenyal Idea Bio-Expander.

Perform the treatment in a suitable facility following the appropriate techniques.

Fill in the adhesive labels included in the package, then apply one on the patient card stored at the doctor's surgery and hand the other to the patient.

Keep away from the reach of children.

In rare cases, the product may cause an allergic reaction.

STORAGE METHODS

Regenyal Idea Bio-Expander must be stored between 2°C and 28°C.

Do not freeze. Do not expose to heat sources.

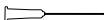
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AGO/NEEDLE **26G x 13mm**



CANNULA/CANNULA **27G x 37mm**



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STERILE EO



NEEDLE CONCEPT

1 Allée Pierre Georges Latécoère
64200 Biarritz
France

09/2019 - rev. 01



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